

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

JS-6

CIVIL MINUTES - GENERAL

Case No. 2:23-cv-05490-SVW-MRW

Date December 9, 2024

Title *United States ex rel. Lockwood v. Sanofi US Services, Inc. et al..*

Present: The Honorable STEPHEN V. WILSON, U.S. DISTRICT JUDGE

Paul M. Cruz

N/A

Deputy Clerk

Court Reporter / Recorder

Attorneys Present for Plaintiffs:

Attorneys Present for Defendants:

N/A

N/A

Proceedings: ORDER GRANTING SANOFI'S MOTION TO DISMISS [78]

I. Introduction

Before the Court is Defendant Sanofi Services Inc. and Defendant Sanofi-Aventis U.S. LLC's (collectively, "Sanofi" or "Defendants") motion to dismiss the second amended complaint filed by Relator John M. Lockwood ("Relator"). ECF No. 78. For the following reasons, the motion is GRANTED.

II. Background

The Court recounted the facts and statutory framework surrounding this case in detail in its previous order dismissing Plaintiff's corrected amended complaint. ECF No. 76. Nonetheless, for the sake of completeness, the Court will repeat much of those facts below.

A. Statutory and Regulatory Framework

Due to the technical nature of this case, it is appropriate to briefly summarize the relevant federal regulations before discussing Relator's allegations.

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i. The Medicaid Drug Rebate Program

To receive Medicare payments, drug manufacturers must participate in the Medicaid Drug Rebate Program (“MDRP”). 42 U.S.C. § 1396r-8(a)(1). The Medicaid Drug Rebate Program requires that manufacturers pay states a per-unit rebate based on the “average manufacturer price” for “each dosage form and strength” of a covered outpatient drug. 42 U.S.C. §§ 1396r-8(c)(1)(A), 2(A)-(B). Specifically, the required rebate is the total units of drug sold to Medicaid providers multiplied by the greater of (1) the “difference between the average manufacturer price and the best price,” or (2) the minimum rebate percentage of such average manufacturer price” (23.1% for rebate periods beginning after 2009). 42 U.S.C. § 1396r-8(c)(1)(A). The “average manufacturer price” is the average price paid to the manufacturer by “wholesalers” and “retail community pharmacies.” *Id.* The “best price” is the “lowest price available from the manufacturer during the rebate period.” 42 U.S.C. §§ 1396r-8(c)(1)(C). Manufacturers also must submit regular reports of certain pricing data. 42 U.S.C. § 1396r-8(b)(3)(A).

Under the MDRP, manufacturers do not pay one rebate for each drug they produce. Rather, they pay a rebate for “each dosage form and strength” of a given drug. 42 U.S.C. §§ 1396r-8(c)(1)(A), 2(A)-(B). So, if a manufacturer produces two versions of drug, and the two versions have different strengths, then a manufacturer must calculate and pay two separate rebates. Importantly, neither the MDRP, nor the Medicaid statute overall, provides a definition for what constitutes a drug’s “strength.”

ii. National Drug Codes

FDA regulations require that each drug have a unique National Drug Code “to identify its labeler, product, and package size and type.” 21 C.F.R. § 207.33(a) A National Drug Code has three parts: (1) a labeler code, which is assigned by the FDA; (2) a product code; and (3) a package code. *Id.* § 207.33(b). For a new drug, manufacturers propose a National Drugs Code to the FDA along with other identifying information. *Id.* § 207.33(d)(1). If the proposed National Drugs Code conforms to the requirements of 21 C.F.R. § 207.33 and is not assigned to a different drug, the FDA assigns the proposed National Drug Code to the new drug. *Id.* § 207.33(d)(2). If, after the initial National Drug Code is assigned, there is a change to “the strength of any active pharmaceutical ingredient” or to “the dosage form” of the drug, then the manufacturer “must propose a new and unique National Drug Code.” *Id.* § 207.35(a)-(b)(3).

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iii. Abbreviated New Drug Application Process

Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (“FDCA”) provides an expedited drug approval process for drugs competing with drugs already approved by the FDA. 21 U.S.C. § 355. Essentially, the FDA allows the applicant to establish the competitor drug’s safety and efficacy using the trials and investigations of an already approved drug that is “pharmaceutically equivalent,” thus saving the applicant from the time and expense of conducting their own trials. 21 C.F.R. § 314.54(a). To qualify for this expedited approval process, the applicant must identify the already approved drug (the “listed” or “reference” drug) upon which the applicant relies. 21 C.F.R. § 314.54(a)(1)(ii). Two drugs are pharmaceutically equivalent if, among other things, they come in “identical dosage forms and routes of administration,” “contain identical amounts of the identical active drug ingredient,” and have the same “identity, strength, quality, and purity, including potency.” 21 C.F.R. § 314.3.

iv. Structured Product Labeling System

The FDA’s Structured Product Labeling (“SPL”) is a “document markup standard” that the FDA uses “as a mechanism for exchanging product and facility information.”¹ Put simply, the SPL is a standard format that the FDA uses to list, store, and communicate information about drugs and drug making facilities.

The SPL first comes into play during the FDA approval process. When applying for a new drug, the manufacturer must submit the “content of labeling required under [21 CFR 201.100] . . . in electronic format.” 21 C.F.R. 314.50(l). Typically, “electronic format” means in SPL format. See SAC Ex. 12 (instructing Sanofi to submit the “content of labeling” for Admelog, as required by 21 CFR 314.15(l), in SPL format). The “content of labeling” required under 21 C.F.R. 201.100 includes the labeling information required under 21 C.F.R. 201.57. 21 C.F.R. 201.57, in turn, requires drug labeling include “the strength or potency of the dosage form [of the drug] in metric system.” Put succinctly, after a drug receives initial FDA approval, the manufacturer must submit certain SPL information to the FDA,

¹ U.S. Food & Drug Administration, Structured Product Labeling Resources, <https://www.fda.gov/industry/fda-data-standards-advisory-board/structured-product-labeling-resources>

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including the strength that will be included on the drug's labeling.

B. Facts

Sanofi is the manufacturer of the drug "Admelog," which is a brand of insulin that patients self-administer via injection. Second Amended Complaint ("SAC") ¶ 62, ECF No. 52. Sanofi sells Admelog in two different forms: Admelog in a 10-milliliter vial ("Admelog 10-ml") and Admelog in a 3-milliliter vial ("Admelog 3-ml"). *See SAC* ¶ 5. Both Admelog products have a concentration of 100 units per ml and are sold in multi-dose vials. ECF No. 78-10.

The FDA approved Admelog 10-ml in 2017 through the Section 505(b)(2) approval process described above. SAC ¶ 123; 21 U.S.C. § 355; 21 C.F.R. § 314.54(a). Sanofi listed the 10-ml version of "Humalog," an insulin product approved by the FDA in 1996, as its reference drug. *Id.* ¶¶ 123, 146. Humalog 10-ml, like Admelog 10-ml, has a concentration of 100 units/ml. *Id.* ¶ 123. After the FDA approved Admelog 10-ml, Sanofi assigned it a National Drug Code, *see id.* ¶ 12; and listed the package type as "vial, multi-dose." *Id.* ¶ 132.

In 2018, Sanofi secured FDA approval for Admelog 3-ml through the same 505(b)(2) approval process. *Id.* ¶¶ 75, 123. Sanofi again listed Humalog as the reference drug, but this time listed the 3-ml Humalog product as the reference drug. *See id.* ¶ 80. Sanofi assigned Admelog 3-ml a new National Drug Code that was different than the National Drug Code for Admelog 10-ml. *Id.* Sanofi listed the package type for Admelog 3 ml as "vial." *Id.* ¶ 132.

When calculating its Medicaid rebate, Sanofi calculated and reported two different average manufacturer prices: one price for Admelog 10-ml and one price for Admelog 3-ml. *Id.* ¶ 213. This, in turn, led Sanofi to pay two different rebate amounts for Admelog 10- and 3-ml respectively. *Id.*

Relator is an experienced medical doctor and was previously a Medicaid provider. *Id.* ¶ 220. Until 2019, Relator was a principle of Ven-A-Care of the Florida Keys, which brought multiple False Claims Act cases against pharmaceutical manufacturers. *Id.*

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C. Procedural History

On July 10, 2023, Relator filed this action on behalf the United States, California, Georgia, Illinois, Indiana, Maryland, Michigan, Nevada, New Jersey, New Mexico, New York, Rhode Island, and Massachusetts, bringing claims under federal and state versions of the False Claims Act. *See Compl.*, ECF No. 1.

The thrust of Relator's allegations is that Sanofi, by (1) reporting separate average manufacturer prices for Admelog 10- and 3-ml and (2) calculating separate Medicaid rebates for each drug, falsely represented to Medicaid that Admelog 10- and 3-ml have different dosage forms and strengths. *Id.* ¶¶ 5, 6. According to Relator, this false representation allowed Sanofi to offer steep discounts on Admelog 3-ml to non-Medicaid providers without increasing the Medicaid rebate it owed on Admelog 10-ml. *Id.* ¶¶ 5, 6, 70, 83. Relator alleges that he discovered Sanofi's misconduct by analyzing the Medicaid Drug Rebate Program drug database using his "specialized, independent knowledge" of Medicaid and the "pharmaceuticals marketplace," as well as his experience in other False Claims Act lawsuits. *Id.* ¶ 223-24.

On February 21, 2024, the United States declined to intervene in the case. ECF No. 25. Sanofi moved to dismiss Relator's initial complaint on May 6, 2024, but the motion was mooted by Relator filing a First Amended Complaint, which was shortly followed by a Corrected First Amended Complaint. ECF 50, 52. Sanofi moved once again to dismiss the case. Def. Mot. to Dismiss, ECF No. 53. While Relator eventually filed an opposition, ECF No. 56; Relator also moved to voluntarily dismiss the case without prejudice. ECF No. 55. The States, however, objected to voluntary dismissal of the case. ECF No. 58.

The Court granted Sanofi's motion to dismiss on September 9, 2024, holding that Plaintiff failed to adequately allege scienter. ECF No. 76. Relator filed a second amended complaint on September 23, 2024. ECF No. 77. Sanofi moved to dismiss the SAC. ECF No. 78. The Court held a hearing on Sanofi's motion on November 19, 2024, and took the matter under submission.

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III. Legal Standard – Motion to Dismiss

A motion to dismiss under Rule 12(b)(6) challenges the legal sufficiency of the claims stated in the complaint. *See Fed. R. Civ. P. 12(b)(6)*. To survive a motion to dismiss, the plaintiff's complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. A complaint that offers mere "labels and conclusions" or "a formulaic recitation of the elements of a cause of action will not do." *Id.*; *see also Moss v. U.S. Secret Serv.*, 572 F.3d 962, 969 (9th Cir. 2009) (citing *Iqbal*, 556 U.S. at 678).

Plausibility "is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 556). On one hand, "[g]enerally, when a plaintiff alleges facts consistent with both the plaintiff's and the defendant's explanation, and both explanations are plausible, the plaintiff survives a motion to dismiss under Rule 12(b)(6)." *In re Dynamic Random Memory (DRAM) Indirect Purchaser Antitrust Litig.*, 28 F.4th 42, 47 (9th Cir. 2022) (citing *Starr v. Baca*, 652 F.3d 1202, 1216 (9th Cir. 2011)). But, on the other, "[w]here a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." *Eclectic Props. E.*, 751 F.3d at 996 (quoting *Iqbal*, 556 U.S. at 678). Ultimately, a claim is facially plausible where "the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *See Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 556).

In reviewing a Rule 12(b)(6) motion, a court "must accept as true all factual allegations in the complaint and draw all reasonable inferences in favor of the nonmoving party." *Retail Prop. Trust v. United Bhd. of Carpenters & Joiners of Am.*, 768 F.3d 938, 945 (9th Cir. 2014). Thus, "[w]hile legal conclusions can provide the complaint's framework, they must be supported by factual allegations. When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Iqbal*, 556 U.S. at 679.

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Importantly, because FCA claims are rooted in fraud, Relator “must overcome a heightened pleading standard under Rule 9(b).” *ESG Cap. Partners, LP v. Stratos*, 828 F.3d 1023, 1031 (9th Cir. 2016). This means that Relator must “state with particularity the circumstances constituting fraud or mistake,’ including ‘the who, what, when, where, and how of the misconduct charged.’” *Ebeid ex rel. U.S. v. Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010) (quoting *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003)). “[M]ere conclusory allegations of fraud” as well as “[b]road allegations that include no particularized supporting detail” are “insufficient.” *United States v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1180 (9th Cir. 2016) (quotations omitted). That said, “a relator is not required to identify actual examples of submitted false claims; instead, ‘it is sufficient to allege particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.’” *Id.* at 1209 (quoting *Ebeid*, 616 F.3d at 998-99).

In sum, Rule 9(b) requires that “the circumstances alleged to constitute fraud be specific enough to give the defendant notice of the particular misconduct so that it can defend against the charge.” *Godecke v. Kinetic Concepts, Inc.*, 937 F.3d 1201, 1208 (9th Cir. 2019). “To state an FCA claim, a relator is not required to identify actual examples of submitted false claims; instead, ‘it is sufficient to allege particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.’” *Godecke*, 937 F.3d at 1209 (quoting *Ebeid*, 616 F.3d at 998-99).

IV. Discussion

A. Federal False Claim Act

The False Claims Act (“FCA”) holds anyone liable who “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval,” or “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.” 31 U.S.C. Section 3729(a)(1)(A), (B). The FCA also provides liability for anyone who “knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.” 31 U.S.C. Section 3729(a)(G). This statutory language boils down to four requirements that must be satisfied to establish an FCA claim: “(1)

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a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due.”” *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 898 (9th Cir. 2017) (quoting *United States ex. Rel. Hendow v. Univ. of Phx.*, 461 F.3d 1166, 1174 (9th Cir. 2006)).

i. Falsity

The foundation of an FCA claim is evidence of a false statement or fraudulent course of conduct. Here, Relator alleges that Sanofi made false statements regarding the strength Admelog 10- and 3-ml. In short, the Medicaid Drug Rebate Program requires manufacturers to report the average manufacturer price and calculate the corresponding Medicaid rebate amount “with respect to each dosage form and strength” of a given drug. 42 U.S.C. §§ 1396r-8(c)(1)(A). Relator alleges that Sanofi, by (1) reporting separate average manufacturer prices for Admelog 10- and 3-ml and (2) calculating separate Medicaid rebates for each drug, falsely represented to Medicaid that Admelog 10- and 3-ml do not have the same “dosage form and strength.” *Id.* ¶¶ 5-6.

The key question, therefore, is whether Admelog 10- and 3-ml have the same “strength” as defined by the Medicaid Drug Rebate Program (the parties do not contest that Admelog 10- and 3-ml have the same dosage form). If they do, then Sanofi’s separate price reports and rebate calculations represent false statements. But if they do not, then Sanofi was not only permitted, but required to report Admelog 10- and 3-ml’s price and rebate amounts separately, meaning Sanofi’s did not make any false statements and Relator’s claims fail.

The answer to this question requires an analysis of how the term “strength” is defined under the MDRP. When the Court dismissed Plaintiff’s Corrected First Amended Complaint, it declined to conduct this analysis. The Court turns to it now and holds that, for the reasons explained below, Admelog 10- and 3-ml do not have the same strength under the Medicaid Drug Rebate Program. Accordingly, Sanofi did not make false statements when it submitted separate Medicaid rebates for Admelog 10- and 3-ml.

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a. The term “strength” in the MDRP should be defined with reference to Section 505 of the FDCA.

The Medicaid Drug Rebate Program (“MDRP”) does not explicitly define the term strength. *See* 42 U.S.C. §§ 1396r-8. Nor does the Medicaid statute at large define strength. The Court also is not aware of any regulation, agency guidance, or court decision that explicitly defines the term “strength” as it is used in the MDRP.

But despite this lack of explicit guidance, traditional rules of statutory interpretation suggest that “strength” in the MDRP should be interpreted with reference to section 505 of the FDCA. This becomes clear when one looks at the broader context surrounding the term “strength” in the MDRP. The MDRP instructs manufacturers to calculate separate rebates for “each dosage form and strength of a single source drug.” 42 U.S.C. § 1396r-8(c)(1)(A). As already noted, the MDRP does not define the term “strength,” but it does define the term “single source drug.” The “usual rule of statutory interpretation [is] that words are to be judged by their context.” *United States v. Carpenter*, 933 F.2d 748, 751 (9th Cir. 1991). The Court will accordingly look to the definition of “single source drug” to define “strength.” *See id.* After all, a word in a statute “is known by the company it keeps.” *Gustafson v. Alloyd Co.*, 513 U.S. 561, 55 (1995).

The MDRP defines “single source drug” as “a covered outpatient drug . . . which is produced or distributed under a new drug application approved the Food and Drug Administration.” 42 U.S.C. § 1396r-8(k)(7)(A)(iv). The statute further defines “covered outpatient drug” as a drug that “is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act or which is approved under section 505(j) of such Act.” *Id.* § 1396r-8(k)(2)(A)(i).

In sum, the definition of “single source drug” under the MDRP explicitly references section 505 of the FDCA, more specifically the FDCA approval process. Since the MDRP defines “single source drug” with reference under to the Section 505 approval process, it only makes sense to define strength the same way, as “words are to be judged by their context.” *See Carpenter*, 933 F.2d at 751.

Interpreting “strength” with reference to section 505 of the FDCA leads to the definition of strength contained in FDA regulations governing new drug applications, specifically 21 C.F.R. § 314.3. Indeed,

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Section 314.3 states that the definitions contained in that section “apply to this part [(Part 314)] and part 320 of this chapter.” Part 314 specifically governs “applications to market a new drug under Section 505 of the [FDCA],” 21 C.F.R. § 314.1(a); including an entire subsection on the “procedure for submission of a 505(b)(2) application.”

Application of the FDA’s definition of strength to the MDRP is affirmed by the fact that the Centers for Medicare and Medicaid Services (“CMS”), the organization in charge of implementing the MDRP, uses the FDA’s² definition of strength to monitor whether manufacturers are complying with the statute. Indeed, CMS guidance states that it “utilizes the . . . data available on Drugs@FDA to be able to determine if a manufacturer’s drugs are reported correctly.”³ This would presumably include using the Drugs@FDA data to determine whether a drug’s strength is reported correctly. Surely, if CMS uses the drug strengths listed on the FDA’s online drug database to determine if manufacturers are correctly implementing the MDRP, then the definition of strength used in that database should be the definition applied to the term “strength” in the MDRP.

- b. The FDA defines the strength of Admelog with reference to both its volume and concentration, such that Admelog 10- and 3-ml do not have the same strength.**

Under the definition of strength contained in 21 C.F.R. § 314.3, Admelog 10- and 3-ml have different strengths. Section 314.3 defines strength as follows:

“Strength is the amount of drug substance contained in, delivered, or deliverable from a drug product, which includes:

- (1)(i) The total quantity of drug substance in mass or units of activity in a dosage unit or container closure (e.g., weight/unit dose, weight/volume or weight/weight in a container closure, or units/volume or units/weight in a container closure);

² The FDA is the agency in charge of implementing the FDCA.

³ Medicaid Drug Rebate Program, National Drug Rebate Agreement (NDRA) Reference Guide at 3 (February 24, 2023), available at <https://www.medicaid.gov/medicaid/prescription-drugs/downloads/ndra-ref-guide.pdf>.

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and/or, as applicable

(ii) The concentration of the drug substance in mass or units of activity per unit volume or mass (e.g., weight/weight, weight/volume, or units/volume); or

(2) Such other criteria the Agency establishes for determining the amount of drug substance contained in, delivered, or deliverable from a drug product if the weights and measures described in paragraph (i) of this definition do not apply (e.g., certain drug-device combination products for which the amount of drug substance is emitted per use or unit time).

21 C.F.R. § 314.3.

To start, based on a plain reading of this definition alone, Admelog 10- and 3-ml have different strengths. The definition reads: “[s]trength is **the amount of drug substance** contained in . . . a drug product.” *Id.* Admelog 10- and 3-ml, while having the same concentration of 100 units/ml, do not have the same amount of drug substance. Admelog 10-ml contains 1,000 units of insulin, while Admelog 3-ml contains 300 units.

But even beyond the definition’s plain language, the FDA’s commentary on Section 314.3’s definition of strength confirms that Admelog 10- and 3-ml have different strengths. When the FDA was proposing this definition of strength in 2015, the FDA clarified that “the strength of a parenteral drug product is determined by both criteria in paragraph (i) of the proposed definition—i.e., the total quantity of drug substance in a container closure **and** the concentration of the drug substance.” 80 Fed. Reg. 6802 at 6818 (emphasis added). Insulin is a parenteral drug, and therefore the FDA’s instruction to consider both the quantity and concentration of drug product would apply to Admelog.

c. The FDA consistently lists Admelog 10- and 3-ml as having different strengths.

The Court’s reading of Section 314.3 and its conclusion that Admelog 10- and 3-ml have different

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strengths is bolstered by the fact that the FDA consistently lists Admelog 10- and 3-ml as having different strengths. For example, and most importantly, the FDA's own drug database—Drugs@FDA—lists Admelog's strength in terms of concentration and strength, such that the database lists Admelog 10- and 3-ml as having different strengths.⁴ This is especially relevant because CMS, which is the entity in charge of implementing the MDRP, explicitly stated that it “utilizes the . . . data available on Drugs@FDA to be able to determine if a manufacturer’s drugs are reported correctly.”⁵ If CMS uses Drugs@FDA data to determine if a drug’s strength is reported correctly under the MDRP, then it stands to reason that “strength” is defined in the MDRP in the same way as it is defined in the Drugs@FDA database. And while the Drugs@FDA database does not provide an explicit definition of strength, it does list Admelog’s strength in terms of both volume and concentration, thus strongly suggesting that the MDRP defines Admelog’s strength in the same way.

Other FDA publications similarly list Admelog’s strength in terms of strength and concentration. For instance, the FDA’s “Orange Book,” which lists drug products approved under Section 505 of the FDCA (including, at the time of its FDA approval, Admelog), gives the following guidance with respect to strength: “the strength of parenteral drug products generally is identified by **both the total drug content and the concentration of drug substance** in a container approved by the FDA.” The Orange Book, 44th Ed. (2024), § 1.7 at xvii (emphasis added). Consistent with this definition, the FDA’s Orange Book listed Admelog 10- and 3-ml’s strength in terms of both their total quantity of insulin and their concentration. The Orange Book, 44th Ed. (2024), § 3-238.

In 2020, the FDA moved Admelog from its Orange Book to its Purple Book, which lists biologic drug products. The Purple Book, like the Orange Book, lists Admelog 10- and 3-ml’s strength as a combination of quantity and concentration. Purple Book, Database of Licensed Biological Products, <https://purplebooksearch.fda.gov/>, (Aug. 14, 2024).⁶

⁴ Federal Drug and Food Administration, Drugs@FDA: FDA-Approved Drugs, <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm> (available by searching for “Admelog” in the search bar).

⁵ Medicaid Drug Rebate Program, National Drug Rebate Agreement (NDRA) Reference Guide at 3 (February 24, 2023). Available by searching for “Admelog” in the search bar.

⁶ Available by searching for “Admelog” in the search bar.

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Similarly, FDA Guidance on Biosimilar Development and the BPCI Act also support the conclusion that Admelog 10- and 3-ml have different strengths. The guidance, which explains how a manufacturer can demonstrate that two products are bioequivalent, explains that: “[i]n general, a sponsor of a proposed biosimilar product . . . with an *injection* dosage form (e.g., a solution) can demonstrate that its product has the same strength as the reference product by demonstrating that both products have *the same total content of drug substance (in mass or units of activity and the same concentration of drug substance (in mass or units of activity per unit volume))*.⁷” ECF 78-5 at 9 (emphasis added).

d. FDA labeling regulations that define Admelog’s strength only in terms of concentration do not apply to the MDRP.

The FDA does not use the same definition of strength in all contexts. While the FDA’s regulations governing new drug approval (i.e., 21 C.F.R. § 314.3) define Admelog’s strength in terms of both concentration and volume, other FDA regulations, namely in the labeling context, define Admelog’s strength only in terms of concentration. As explained below, however, the definitions of drug strength contained in these labeling regulations do not apply to the MDRP.

There are three relevant labeling regulations at issue: (1) the United States Pharmacopeia; (2) the FDA’s Structured Product Labeling System (“SPL”); and (3) FDA guidance on drug product labeling. The Court will address each in turn.

United States Pharmacopeia

The United States Pharmacopeia is a nonprofit organization that sets standards for the quality and safety of medicines. Relator points to the USP’s chapter on labeling, which explains that “Insulin products are an example of a product class that is an exception from the total drug content per container requirement.” USP General Chapter <7> Labeling, page 2 (2019).⁷

This guidance, however, is contained in the USP’s chapter on labeling, and thus its impact is limited to context of drug labeling. The FDA makes this clear in guidance that explains that a drug’s

⁷ Available at https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/revisions/gc-7-labeling-rb-notice-20190830.pdf.

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strength is not always the same as the definition of strength used in the USP. For example, in its guidance interpreting Section 314.3, the regulation that outlines how the FDA defines strength for new drug applications, the FDA explained that: “[a]lthough the USP naming policy describes the ‘strength’ of a drug product as the amount of active moiety present in the product, the strength of the drug product for purposes of 505(j)(2)(A)(iii) of the FD&C Act is the amount of the drug substance.” 80 Fed. Reg. at 6816.

More importantly, nothing in the MDRP suggests that USP guidelines should apply to the definition of “strength.” In contrast, there is reason to find that the definition of strength used in the FDA new drug approval process should apply to the MDRP’s definition of strength. Indeed, as explained above, the MDRP’s definition of “single source drug,” which is the object that the term “strength” is attached to, explicitly references the Section 505 drug approval process, which itself uses the definition of strength contained in 21 C.F.R. § 314.3. Section 314.3, unlike the USP, defines Admelog’s strength in terms of both volume and concentration.

Structured Product Labeling System

Structured Product Labeling is a standard format the FDA uses when listing drug information electronically. Manufacturers first submit SPL information to the FDA after a drug receives initial FDA approval. *See* SAC Ex. 12. Part of the information submitted is a drug’s strength. *See* 21 C.F.R. 314.50(l); 21 C.F.R. 201.57; SAC Ex. 1.

The FDA has specific rules for how manufacturers should express a drug’s strength in SPL listings. Indeed, the FDA’s guidance on “Strength Conversion in Drug Listing” starts with: “a drug strength or concentration of its active ingredient(s)/active moiety can be expressed in many ways.” ECF 78-7. With respect to “injectable products that are liquids,” the FDA’s guidance instructs that “the active ingredient in SPL should be listed as the total amount per total volume.” *Id.*

Footnote number 2 in this guidance, however, makes clear that there are exceptions to this general rule. Insulin is one of these exceptions. As explained in the United States Pharmacopeia’s chapter on labeling, “Insulin products are an example of a product class that is an exception from the total drug

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content per container requirement.” USP General Chapter <7> Labeling, page 2 (2019).⁸

Zooming back out, the FDA’s guidance on “Strength Conversion in Drug Listing” and the United States Pharmacopeia, together, prompt manufacturers to express the strength of insulin in SPL files in terms of concentration only. But that SPL defines strength in this way does not mean that that is how the MDRP defines strength. Quite the contrary, none of the language in the MDRP directs manufacturers to reference SPL data to define any of the MDRP’s terms, including strength. By contrast, the MDRP, through its definition of “single source drug,” explicitly references the Section 505 drug approval process, which defines insulin strength in terms of concentration and volume.

Nor do any SPL regulations or guidance state that CMS will apply the expression of strength in SPL listings to the MDRP. In fact, relevant CMS guidance states the opposite, as CMS guidance states that it will use the data contained in the Drugs@FDA database.⁹ And, as explained above, that database defines Admelog’s strength in terms of concentration and volume.

To be sure, there is CMS guidance indicating that CMS sometimes references SPL data to verify if a drug product is eligible for coverage under the MDRP. But importantly, there is no evidence that CMS uses SPL data to determine drug strength. CMS guidance from 2012 states: “we request that you ensure that your company’s drug information is updated and listed electronically with FDA as we will be utilizing FDA’s [NDC Structured Product Labeling Data Elements] file to obtain or verify drug information for purposes of MDRP.” SAC ¶ 71 n.70. Similarly, CMS guidance from 2013 also encourages “all manufacturers to review the Food and Drug Administration’s (FDA) comprehensive NDC Structured Product Labeling (SPL) Data Elements file (NSDE)” because “CMS uses listing information to help verify which drug products are eligible for coverage under the MDRP.” SAC ¶ 71 n.71.

This guidance does not support Relator’s position that MDRP uses the SPL’s definition of strength. To start, the guidance explains that CMS is going to use information from the FDA’s NDSE file, not SPL drug listing information at large. NDSE files only contain a subset of information contained in SPL files,

⁸ Available at https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/revisions/gc-7-labeling-rb-notice-20190830.pdf.

⁹ Medicaid Drug Rebate Program, National Drug Rebate Agreement (NDRA) Reference Guide at 3 (February 24, 2023). Available by searching for “Admelog” in the search bar.

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and, notably, they do not contain information regarding drug strength.¹⁰ Even if the NDSE file did contain information regarding drug strength, the CMS guidance explains that CMS will use the listing information to “verify which drug products are eligible for coverage under the MDRP,” not to determine drug strength.

FDA Guidance on Drug Product Labeling

The FDA’s guidance on drug product labeling instructs that the labels on insulin products should list the products’ strength in terms of concentration only: “For insulin products, generally the only expression of strength should be the quantity in units per milliliter because only a portion of the supplied total volume is typically administered at a time.”¹¹ See SAC ¶¶ 143-144.

Similarly to the United States Pharmacopeia, however, this guidance is explicitly limited to the drug labeling context. Indeed, the introduction section to this guidance reads: “[t]his guidance focuses on safety aspects of the application holder’s container label and carton labeling design.” See *id.* And, as was the case with the USP and SPL, nothing in the MDRP suggests that the FDA’s guidance on drug product labeling should apply to the MDRP’s definition of “strength.”

In sum, the Court holds that the MDRP defines drug strength by applying the definition of “strength” that the FDA uses when considering new drug applications. Namely, the definition of strength contained in 21 C.F.R. § 314.3. Based on this definition, and all the applicable regulations and guidance, Admelog’s strength is defined in terms of *both* its concentration and volume. Any contrary definitions—namely, the strength definitions contained in the FDA’s SPL guidance and labeling guidelines—do not apply to the MDRP. Admelog 10- and 3-ml therefore do not have the same strength, meaning Sanofi did not make false statements when it submitted separate rebates for Admelog 10- and 3-ml. In short, the Court finds that Relator has failed to allege falsity.

¹⁰ Food and Drug Administration, NSDE, <https://www.fda.gov/industry/structured-product-labeling-resources/nsde>.

¹¹ U.S. Depart of Health and Human Services Food and Drug Administration, Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors at 15-16 (May 2022).

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ii. Scienter

In the alternative, even if the MDRP did define Admelog’s strength in terms of concentration only such that Sanofi made false statements in its Medicaid rebates, Relator fails to plausibly allege scienter.

a. Legal Standard for Alleging Scienter

To establish an FCA claim, a relator must establish that the defendant acted with scienter. *Campie*, F.3d at 898. Scienter requires that the defendant violated the FCA “knowingly,” which is defined as “actual knowledge” of the information,” “act[ing] in deliberate ignorance,” or “in reckless disregard” of the information’s truth or falsity. 31 U.S.C. § 3729(b)(1). “The FCA’s ‘knowingly’ requirement ‘require[s] no proof of specific intent to defraud.’” *Godecke*, 937 F.3d at 1211 (quoting 31 U.S.C. § 3729(b)(1)(B)). “Instead of pleading specific intent to defraud, it is sufficient to plead that the defendant knowingly filed false claims, or that the defendant submitted false claims with reckless disregard or deliberate ignorance as to the truth or falsity of its representations.” *Id.* What’s more, “under Rule 9(b), scienter need not be pleaded with particularity, but may be alleged generally.” *Winter ex rel. United States v. Gardens Reg’l Hosp. & Med. Ctr.*, 953 F.3d 1108, 1122 (9th Cir. 2020).

1. To plead an FCA claim, relators must allege facts supporting a plausible inference of scienter.

Just because scienter may be alleged generally, however, does not mean that conclusory or vague allegations that a defendant “knew” or “had knowledge” of fraud is sufficient. Quite the contrary, the FCA’s scienter requirement is “rigorous.” *United States v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1176 (9th Cir. 2016). Accordingly, rather than plead conclusory assertions regarding a defendant’s knowledge, a relator’s complaint “must set out sufficient factual matter from which a defendant’s knowledge of fraud might reasonably be inferred.” *United States ex rel. Silingo v. Wellpoint, Inc.*, 904 F.3d 667, 679-80 (9th Cir. 2018). Put differently, a complaint must “allege facts supporting a plausible inference of scienter.” *Winter*, 953 F.3d at 1122 (9th Cir. 2020). Often, this is done by alleging that the defendant “took internal actions perpetuating its fraud,” such as actions to conceal its fraud or otherwise deceive government entities. See, e.g., *United States ex rel. Campie*, 862 F.3d 890, 904 (9th Cir. 2017)

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(finding scienter where the relator alleged that the defendant “took internal actions perpetuating its fraud,” such as “altering test results, batch numbers, and inventory control numbers, and representing that nonapproved [drug product] came from [FDA] approved facilities”); *Godecke v. Kinetic Concepts, Inc.*, 937 F.3d 1201, 1208 (9th Cir. 2019) (finding scienter where the relator alleged that the defendant had internal tracking procedures to help conceal its false Medicare claims and where the Defendant fired the relator after she raised concerns regarding false Medicare claims to her superiors).

2. There is no scienter if the defendant made false statements in reliance on a good faith interpretation of the law.

If a relator fails to allege specific facts in support of scienter, the FCA claim fails. *See Winter*, 953 F.3d at 1122 (9th Cir. 2020) (“A [FCA] complaint [must] allege facts supporting a plausible inference of scienter.”). Critically, “‘innocent mistakes, mere negligent misrepresentations and differences in interpretations’ will not suffice to create liability.” *United States v. Corinthian Colleges*, 655 F.3d 984, 996 (9th Cir. 2011) (quoting *Hendow* 461 F.3d at 1174). “A [defendant] relying on a good faith interpretation of a regulation is not subject to [FCA] liability.” *U.S. ex rel. Oliver v. Parsons Co.*, 195 F.3d 457, 460 (9th Cir. 1999).

3. Relators cannot just allege facts that render scienter possible—the allegations must render scienter plausible.

To be clear, at the motion to dismiss stage, the relator does not need to show that it is implausible that the Defendant relied on a good faith interpretation of a regulation. Alleging facts supporting a plausible inference of scienter—i.e., that the defendant knowingly made a false statement—does not require disproving any alternative explanations for the defendant’s behavior. Indeed, “[i]f there are two alternative explanations, one advanced by defendant and the other advanced by plaintiff, both of which are plausible, plaintiff’s complaint survives a motion to dismiss under Rule 12(b)(6).” *Starr*, 652 F.3d 1202, 1216 (9th Cir. 2011).

But if the Court is “faced with two possible explanations, only one of which can be true and only one of which results in liability, plaintiffs cannot offer allegations that are ‘merely consistent with’ their

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favored explanation but are also consistent with the alternative explanation. Something more is needed, such as facts tending to exclude the possibility that the alternative explanation is true, in order to render plaintiffs' allegations plausible within the meaning of *Iqbal* and *Twombly*." *In re Century Aluminum Co. Sec. Litig.*, 729 F.3d 1104, 1108 (9th Cir. 2013). This rule "is consistent with [the Ninth Circuit's] opinion in *Starr v. Baca*, where there were two *plausible* explanations in contention." *Id.* (emphasis in original). If, "however, [the plaintiff's] explanation is merely *possible* rather than *plausible*," then the plaintiff fails to state a claim. *Id.* (emphasis in original).

Moving to the allegations in this case, the key question for the Court is whether Relator "allege[d] facts supporting a plausible inference of scienter." *See Winter*, 953 F.3d at 1122 (9th Cir. 2020). Or, put more specifically, did Relator allege facts supporting a plausible inference that Sanofi knew that the Medicaid Drug Rebate Program ("MDRP") defined the strength of Admelog in terms of concentration only, such that Admelog 10- and 3-ml would have the same strength. If Sanofi knew this, then Sanofi would have known that it was submitting a false statement to Medicaid when it submitted two separate rebates for Admelog 10- and 3-ml.

Analysis of Relator's allegations in his SAC reveal that the answer is no, Relator does not allege facts supporting a plausible inference that Sanofi knew that the MDRP defined strength in terms of concentration only. Rather, Relator alleges facts that make it "merely possible" that Sanofi acted with scienter, rather than plausible. *See Century*, 729 F.3d at 1108. Indeed, while the facts alleged by Relator are certainly "consistent with" Sanofi believing that the MDRP defined Admelog's strength exclusively in terms of concentration, every fact alleged by Relator "is also consistent with the alternative explanation" that Sanofi "rel[ied] on a good faith interpretation of [the MDRP]" and concluded the MDRP defined Admelog's strength in terms of both volume *and* concentration. *See Century*, 729 F.3d at 1108. Under this alternative explanation, Sanofi is not liable under the FCA, as "differences in interpretations will not suffice to create [FCA] liability." *See Corinthian Colleges*, 655 F.3d at 996. Relator fails to rebut Sanofi's alternative explanation with any allegations "tending to exclude the possibility that the alternative explanation is true," including any allegations that Sanofi attempted to conceal its conduct or otherwise deceive government entities. *See Century*, 729 F.3d at 1108.

To demonstrate this lack of scienter, the Court will analyze each of Relator's factual allegations in

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support of scienter in turn.

b. Relator's factual allegations do not create a plausible inference of scienter.

1. The Relevant Statutes and Regulations

First up are the relevant statutes and regulations themselves—i.e., the MDRP and related FDA regulations. This regulatory framework is relevant to the question of scienter because, if the relevant laws and regulations clearly stated that insulin strength under the MDRP is defined only in terms of concentration, then it would certainly be plausible that Sanofi knowingly violated the MDRP when it submitted different rebates for the two drugs. After all, this hypothetical version of the regulatory framework would have provided Sanofi with clear notice that Admelog 10- and 3-ml, which have the same concentrations, have the same strength under the MDRP, and correspondingly, that submitting separate rebates for the two drugs would violate the statute.

But as explained in the section on falsity, even assuming that Plaintiff's argument that the MDRP defines insulin strength only in terms of concentration is correct, there are still myriad regulations and authority suggesting that insulin strength is defined by both concentration *and* volume. Indeed, the FDA's own online database—Drugs@FDA—lists Admelog's strength by both concentration and volume. It is entirely plausible that Sanofi read these regulations and in good faith determined that the MDRP defined Admelog's strength based on both volume and concentration.

Accordingly, not only do the relevant laws and regulations fail to render it plausible that Sanofi knew that Admelog 10- and 3-ml had the same strength under the MDRP, but they are also entirely consistent with Sanofi, in good faith, interpreting the relevant FDA regulations and concluding that Admelog 10- and 3-ml had different strengths. “A [defendant] relying on a good faith interpretation of a regulation is not subject to [FCA] liability.” *Oliver*, 195 F.3d at 460.

2. Structured Product Labeling System

Relator's next factual allegation is that Sanofi listed Admelog 10- and 3-ml's strength in terms of concentration only in its Structured Product Labeling (“SPL”) file. SAC ¶ 133. The question for the Court

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is whether Sanofi defining strength in terms of concentration in an SPL file makes it plausible that Sanofi knew that the MDRP defines the strength of Admelog in terms of concentration only.

The answer is no, Sanofi's expression of strength in the SPL does not render Relator's scienter allegations plausible. Independent of the requirements of the MDRP, the FDA has specific rules for how manufacturers should express a drug's strength in SPL listings, including that insulin strength should be expressed in the SPL by its concentration only.¹² That is, of course, exactly what Sanofi did. When Sanofi submitted its SPL files for Admelog, it listed the strength in terms of its concentration only, just as is required by the relevant SPL regulations.

That Sanofi listed Admelog's strength in terms of concentration in its SPL file, however, is not evidence that Sanofi believed that the MDRP defined strength by concentration only. Rather, it is merely evidence that Sanofi was complying with SPL regulations, which, without any reference to the MDRP, explicitly instruct manufacturers to list insulin strength by concentration. Indeed, no matter how Sanofi conceived of the definition of strength in the MDRP, Sanofi would have still defined strength in Admelog's SPL file in terms of concentration, as that is what FDA guidance and regulations require. That Sanofi listed Admelog's strength in terms of concentration only in its SPL file thus provides no insight into how Sanofi viewed the definition of strength in the MDRP.

For the same reasons, that Sanofi expressed the strength of its other insulin drug products in terms of concentration in their respective SPL files also does not render Relator's allegations plausible. See SAC Exs. 7-10. Sanofi expressing the strength of insulin products in terms of concentration in SPL files does not shed light on whether Sanofi believed that the MDRP defined insulin exclusively in terms of concentration. Indeed, no matter what Sanofi believed about "strength" in the MDRP, SPL regulations and guidance would still have required Sanofi to express the strength of insulin products in SPL files exclusively in terms of concentration.

¹² See the FDA's guidance on "Strength Conversion in Drug Listing," ECF No. 78-7; as well as the United States Pharmacopeia's chapter on labeling. USP General Chapter <7> Labeling, page 2 (2019).

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3. Admelog's Packaging and Labeling

Relator's next relevant allegation in support of its scienter argument is that Admelog's packaging describes Admelog's strength in terms of concentration only. As a threshold issue, it is not clear that this is actually true. As shown in Relator's SAC, Admelog's packaging displays both its concentration and its total volume. *See SAC ¶ 134.* The packaging also does not explicitly tell consumers what the official "strength" of Admelog is. Indeed, the word "strength" does not appear on the packaging at all. *See id.* Similarly, the "Dosage Forms and Strength" section of Admelog's labeling file lists both the concentration and volume of the drug without specifying that one of those measurements is the official measurement of strength. *See SAC Ex. 1 at 1.* That said, it is certainly true that Admelog's packaging and labeling displays its concentration more prominently than its volume, which arguably demonstrates that Admelog's labeling and packaging describes the drug's strength in terms of concentration only.

But even if Admelog's labeling displays its strength in terms of concentration, this does not render Relator's scienter arguments any more plausible, as Admelog's labeling has no relation to how Sanofi conceived of the definition of strength in the MDRP. Indeed, no matter what Admelog believed about the definition of strength in the MDRP, it would have still listed Admelog's strength exclusively in terms of concentration on its labeling and packaging, as that is what the FDA's labeling rules explicitly require. *See SAC ¶¶ 143-44, 158.* Evidence regarding Admelog's labeling is therefore still "consistent with [Sanofi's] alternative explanation" that it relied on a good faith interpretation of the MDRP." *See Century, 729 F.3d at 1108.* Allegations regarding Admelog's labeling thus do not aid Relator's scienter argument.

4. Reference to Humalog

Relator contends that Sanofi representing that Admelog 10- and 3-ml had the same strength as Humalog 10- and 3-ml during the FDCA 505(b) approval process creates a plausible inference of scienter. Not so. As explained in the Court's previous order, that Sanofi represented that Admelog 10- and 3-ml had the same strength as Humalog 10- and 3-ml is not evidence that Sanofi knew that Admelog 10- and 3-ml had the same strength or that Sanofi knew that drug strength was defined only by concentration. Indeed, no matter if you measure strength in terms of concentration only or in terms of concentration and quantity, Admelog 10- and 3-ml still have the same strength as Humalog 10- and 3-ml. Sanofi's use of

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Humalog 10- and 3-ml as their reference drugs for Section 505 approval therefore sheds no light on what definition of strength Sanofi believed to be true.

5. National Drug Codes

Relator also repeats its contention that Sanofi giving Admelog 10- and 3-ml different National Drug Codes creates a plausible inference of scienter. Again, Relator is mistaken. Giving the two products different National Drug Codes provides no insight into how Sanofi conceived of the definition of strength. The FDA requires that a new National Drug Code include a new product code “when there is a change to . . . the strength of any active pharmaceutical ingredient.” 21 C.F.R. 207.35(b)(2). If Sanofi had in good faith interpreted “strength” as a combination of concentration *and* quantity, then it would have also in good faith believed that it was required to assign Admelog 3-ml a different product code than Admelog 10-ml.

6. Differential Pricing Strategy

Finally, the Court reaffirms that Sanofi’s differential pricing strategy is not inconsistent with Sanofi interpreting the Medicaid Drug Rebate Program statute in good faith, and therefore does not create a plausible inference of scienter. Sanofi sells Admelog 3-ml at a higher per-milliliter price compared to Admelog 10-ml. SAC ¶ 83. Sanofi also offers steep discounts on Admelog 3-ml when selling to hospital providers. *Id.* According to Relator, this pricing, combined with the fact that Sanofi calculates separate Medicaid rebates for Admelog 10- and 3-ml, “enables Sanofi to offer deep discounts on the Admelog 3 ml vial, while deceptively excluding its deepest discounts from its quarterly determinations of Best Price for the 10 ml vial,” therefore decreasing its Medicaid rebate obligations. *Id.* ¶ 70.

But even if Sanofi did sell Admelog 10- and 3-ml at different price points, and even if this pricing provided Sanofi with some financial advantage (which is not established), Admelog’s pricing has no bearing on whether Sanofi knew that it was violating the terms of the MDRP when it calculated separate rebates for Admelog 10- and 3-ml.¹³ In short, Admelog’s pricing is unrelated to the question of scienter.

¹³ As an aside, the Court is also skeptical of Relator’s assertion that Sanofi offering steep discounts on Admelog 3-ml when selling to hospital providers is evidence of misconduct. Generally speaking, it is well established in the business world that

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7. Relator's Remaining Allegations of Scienter

Relator's remaining allegations of scienter are conclusory assertions that Sanofi "knew" that Admelog 10- and 3-ml had the same strength under the MDRP. These allegations are conclusory and serve as mere "formulaic recitation[s] of the elements" of scienter and are thus insufficient to establish plausibility. *See Iqbal*, 556 U.S. at 678.

c. Relator fails to allege facts that would typically render scienter plausible.

When courts find that relators sufficiently allege scienter, they often do so based on allegations that the defendant attempted to conceal its wrongful conduct or deceive government entities—i.e., allegations that the defendant "took internal actions perpetuating its fraud." *Campie*, 862 F.3d at 896. Take *United States ex rel. Campie*, 862 F.3d 890, 904 (9th Cir. 2017), for example. There, the relator alleged that Defendant Gilead Sciences violated the FCA by knowingly making false representations to the FDA that it was producing its drug products in registered FDA facilities, when really it was producing drugs in unregistered facilities. *Id.* at 896. To establish scienter, the relators alleged that the defendant "took internal actions perpetuating its fraud," such as "altering test results, batch numbers, and inventory control numbers, and representing that nonapproved [drug product] came from [FDA] approved facilities." *Id.* at 904. The Court held that these allegations were sufficient to establish scienter because they demonstrated that Defendant made the false statements at issue with "knowledge of the falsity and with intent to deceive." *Id.*

Similarly, in *Godecke v. Kinetic Concepts, Inc.*, 937 F.3d 1201, 1208 (9th Cir. 2019), the Court found that the relator adequately alleged scienter because the relator made specific factual allegations showing that the defendant knew its statements were false. In *Godecke*, the relator alleged that the defendant submitted false claims to Medicare. *Id.* at 1205. Specifically, the relator alleged that the defendant falsely represented that it obtained detailed written orders from a physician before delivering durable medical equipment to Medicare patients, as required by Medicare. *Id.* To support scienter, the

manufacturers generally give greater price concessions to purchasers of great volume, such as hospital providers.

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relator made several specific factual allegations showing that the defendant knew its statements were false. For example, the relator alleged that she personally “set up tracking systems specifically for following up on orders for [equipment] that had been delivered but did not satisfy the [Medicare] requirements.” *Id.* at 1211-12. She further alleged that a former employee of the defendant told her that management was aware that they were delivering medical equipment prior to obtaining written orders, in violation of Medicare regulations. *Id.* And finally, the relator alleged that after she raised concerns to her superiors about whether the defendant was following proper procedure for billing to Medicare, the defendant “quickly fired not only [the relator], but also her supervisor, and the senior vice president to whom they both reported.” *Id.* at 1212. The Court held that, together, these “allegations of scienter were sufficient.” *Id.*

Here, unlike *Campie* and *Godecke*, Relator fails to allege any facts showing that Sanofi attempted to conceal its misconduct or otherwise deceive government entities. Rather, Sanofi’s actions were public for all to see. Sanofi made no attempt to hide that it gave Admelog 10- and 3-ml different National Product Codes or that it submitted separate Medicaid rebates for the two drugs. In fact, these actions were so public that Relator, who is not employed or associated with Sanofi, was able to discover that Sanofi submitted different Medicaid rebates for Admelog 10- and 3-ml. Surely if Sanofi was knowingly submitting false statements to Medicaid, it would have made some attempt to conceal its conduct.

Sanofi’s openness stands in stark contrast to the defendants in *Campie* and *Godecke*, where the relators adequately alleged scienter. In *Campie*, the relator alleged that the defendant “took internal actions perpetuating its fraud,” such as “altering test results, batch numbers, and inventory control numbers.” See *Campie*, 862 F.3d at 904. And in *Godecke*, the relator alleged that the defendant “set up tracking systems” to track falsely submitted Medicare claims and also fired the relator immediately after she raised concerns about false claims. See 937 F.3d at 1211-12. Relator fails to make any similar allegations of “internal actions perpetuating [Sanofi’s] fraud” in this case. See *Campie*, 862 F.3d at 904; *Godecke*, 937 F.3d at 1211-12.

Not only are there no allegations that Relator failed to conceal its conduct, but there are no allegations of communications between Sanofi employees demonstrating an intent or plan to submit false Medicaid rebates. By contrast, in *Godecke*, the relator alleged that a former employee of the defendant told the relator that members of the defendant’s management was aware that the defendant company was

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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

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violating Medicare violations. *See* 937 F.3d at 1212.

To be sure, the Court acknowledges that the specific facts of *Campie* and *Godecke* do not set the standard for establishing scienter. But these cases nonetheless demonstrate the point that scienter almost always requires some badge of fraud, typically in the form of concealment on the part of the defendant. As explained in this order, no such badge of fraud is present in Relator's allegations. Rather, Relator's allegations merely show that Sanofi, in plain view of the government, applied different definitions of strength in different contexts, as is required by the pertinent regulations.

In sum, given that Sanofi's actions are consistent with a good faith interpretation of the Medicaid statute, the absence of any allegations that Sanofi tried to conceal its conduct or otherwise deceive Medicaid renders Relator's scienter allegations implausible.

B. State False Claims Statutes

In addition to bringing claims under the federal False Claims Act, Relator brings equivalent state law claims. Just as with the federal False Claims Act, these state law claims require scienter.¹⁴ Accordingly, just as Relator's federal False Claims Act claims fail for a lack of scienter, so too do Relator's state claims.

V. Conclusion

For the foregoing reasons, the court GRANTS Sanofi's motion to dismiss.

¹⁴ See Cal. Gov't Code § 12651; *United States v. Kiewit Pac. Co.*, No. 12-CV-02698-JST, 2013 WL 5770514, at *9 (N.D. Cal. Oct. 24, 2013) (falsity and scienter are elements of FCA and CFCA); O.C.G.A. § 49-4-168.1; *Murray v. Cnty. Health Sys. Prof'l Corp.*, 811 S.E.2d 531, 537 (Ga. App. 2018) ("The statutory language in the GFMCA . . . mirrors the language in the federal [FCA]."); 740 Ill. Comp. Stat. § 175/3; *People ex rel. Stephen B. Diamond, P.C. v. Henry Poole & Co., Ltd.*, 229 N.E.3d 456, 462 (Ill. App. 2023) ("The Illinois [FCA] closely mirrors the federal [FCA]."); Ind. Code § 5-11-5.7-2; *U.S. ex rel. Swiney v. Cnty. Integration Support Servs.*, No. 1:20-cv-00717-JMS-TAB, 2022 WL 2916566, at *5 (S.D. Ind. July 25, 2022) ("The IFCA is the nearly identical Indiana state law equivalent of the FCA."); Md. Code Ann., Health-Gen. § 2-602(a); *Simmons v. UM Cap. Region Health, Inc.*, No. CV 8:21-002074-PX, 2022 WL 2065932, at *3 (D. Md. June 8, 2022) (At its heart, the [MFCA and FCA] prohibit any person from presenting 'a false or fraudulent claim for payment or approval' to the government"); Mass. Ann. Laws Ch. 12, § 5B; *U.S. ex rel. Martino-Fleming v. South Bay Mental Health Ctrs.*, 540 F. Supp. 3d 103, 116-17 n.5 (D. Mass. 2021); Mich. Comp. Laws Serv. § 400.603; *U.S. ex rel. Sheoran v. Wal-Mart Stores East, LP*, 858 Fed. App'x 876, 880 (6th Cir. 2021) (noting that "the FCA and MMFCA are identical in every relevant respect here and are frequently analyzed in tandem"); Nev. Rev. Stat. § 357.040; *U.S.*

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In its previous order, the Court informed Relator that if he did not correct the deficiencies in his allegations regarding scienter in his Second Amended Complaint, that the Court would dismiss his claims with prejudice. Relator's Second Amended Complaint failed to correct these deficiencies, and thus the Court will dismiss Relator's claims WITH PREJUDICE.

IT IS SO ORDERED.

ex rel. Welch v. My Left Foot Children's Therapy, LLC, No. 2:14-cv-01786-MMD-GWF, 2017 WL 1902159, at *1 (D. Nev. May 9, 2017); N.J. Stat. Ann. § 2A:32C-3; *Scibetta v. AcclaiMed Healthcare*, No. 3:16-cv-02385(PGS)(DEA), 2021 WL 5450296, at *6 (D.N.J. Nov. 22, 2021) ("The [NJ FCA] contains similar prohibitions as its federal counterpart."); N.M. Stat. Ann. § 27-14-4; *U.S. ex rel. Hernandez-Gil v. Dental Dreams, LLC*, 307 F. Supp. 3d 1224, 1240 (D.N.M. 2018) ("Under the FCA, . . . and MFCA, the plaintiff must show that the false claims were presented to the government knowingly.") (cleaned up); N.Y. State Fin. Law § 189; *Liss v. Heritage Health & Hous., Inc.*, No. 1:19-cv-4797-LTS-SDA, 2023 WL 2267366, at *5 (S.D.N.Y. Feb. 28, 2023) ("New York courts rely on federal FCA precedents when interpreting the NYFCA.") (cleaned up); R.I. Gen. Laws § 9-1.1-3; *U.S. ex rel. Carbon v. Care New England Health Sys.*, 567 F. Supp. 3d 355, 359 n.8 (D.R.I. 2021) ("Rhode Island [FCA] is nearly identical to the federal [FCA].")

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